Validation of the International Classification of Functioning, Disability and Health Core Set for Obstructive Pulmonary Diseases in the perspective of adults with asthma

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ABSTRACT

Purpose: To validate the Comprehensive and Brief International Classification of Functioning, Disability and Health Core Sets for Obstructive Pulmonary Diseases from the perspective of adults with asthma.

Methods: This was a qualitative, cross-sectional study. Individual interviews with questions related to the disease and its impact on the patient's life were performed. The meaning condensation procedure was used for analysis.

Results: Thirty-five participants (26 females, 41±13 years old) were interviewed. A total of 405 concepts were identified, and 348 were associated to the components Body Functions (n=168), Body Structures (n=22), Activities and Participation (n=33), Environmental Factors (n=125). These concepts were linked to 61 categories: second level (n=25), third level (n=33), fourth level (n=3), which confirmed 41% and 77% of those included in the Comprehensive and Brief Core Sets, respectively. Twenty-four additional categories were identified, and 57 concepts could not be linked to the classification.

Conclusion: The International Classification of Functioning, Disability and Health Core Sets for Obstructive Pulmonary Diseases were supported by the perspective of adults with asthma. The Brief version seemed the best reference for rehabilitation, reflecting the typical disabilities and impairments of these patients. Unconfirmed and added categories have been reported, and their analysis may assist future document updates.

Keywords: ICF, validation studies, asthma, obstructive pulmonary diseases, chronic disease, rehabilitation.

Introduction

Asthma is a major non-communicable respiratory disease, affecting approximately 300 million people worldwide [1]. It is characterised by chronic airway inflammation and a variable airflow limitation, and it is usually associated with airway hyperresponsiveness to direct or indirect stimuli [2]. The main symptoms are dyspnoea, wheezing, chest tightness and cough, which limit patients' daily activities and contribute to poor quality of life [2-4].

Patients with asthma commonly report feelings of anxiety and concerns about the condition and treatment [4,5]. These experiences may worsen the perception of symptoms, increasing the risk for exacerbations and hospitalisations [2,4]. Moreover, such symptoms and experiences are followed by limitations on physical activities and disability [1,6], which, in turn, can be influenced by contextual factors, including health and social support, and job demands [7,8]. Therefore, health professionals need to assess all the relevant health domains according to the perspective of the patient [2,9,10].

The International Classification of Functioning, Disability and Health (ICF) is a framework [11] that may support the clinical rationale of health professionals regarding patients' functioning and health experience, overcoming the disease-centred approach [12,13]. It describes the different health domains from a biological, individual and social perspective. However, its high number of categories (i.e., 1424) makes the framework unfeasible to use in everyday clinical practice. Such difficulty has motivated the development of ICF Core Sets, which represent a selection of the most important ICF categories for a specific health condition [14].

Currently, the Comprehensive and Brief ICF Core Sets for obstructive pulmonary diseases (OPD) are the most appropriate for use in patients with asthma [10,15]. It were developed according to experts in respiratory medicine [10], but not taking account the perspective of patients. The World Health Organization has been encouraging the inclusion of

the patients' perspective to guide health actions [16], and thus, the ICF Core Sets for OPD have been validated from the perspective of patients with chronic obstructive pulmonary disease (COPD) [17,18]. As it is well known patients with asthma experience significant differences from COPD [15], a validation considering this population may allow a more widespread application of the ICF. Therefore, this study aimed to validate the Comprehensive and the Brief ICF Core Sets for OPD from the perspective of adults with asthma.

Material and Methods

Study design

A qualitative, cross-sectional study, based on interviews of adults with asthma, was conducted at a study centre in ----, ----. The present study was approved by the institutional research ethical committee (----), and patients provided their written informed consent prior to any data collection.

Subjects

Clinically stable adults with asthma (i.e., no exacerbation in the last three months) were identified as potentially eligible by the pulmonologist during routine medical appointments, and were referred to the researchers, who provided additional information about the study and invited patients to enrol. Patients were included if they were i) diagnosed with asthma (International Statistical Classification of Diseases and Related Health Problem-10, as code J45) according to the Global Initiative for Asthma (i.e., history of variable respiratory symptoms and confirmed variable expiratory airflow limitation) [2]; ii) aged between 20 and 70 years old; and iii) had an Asthma Control Test above 18 points [19,20]. Patients were excluded if they were i) current smokers; ii) presented psychiatric, cardiac or neurological conditions; and/or iii) were not able to understand or carry out any of the study procedures.

Data collection

Socio-demographic (gender, age, education level) and anthropometric data (weight, height and body mass index) were first collected. Lung function was assessed with a calibrated spirometer Koko® PFT system version 4.1 (nSpireHealth Inc., Louisville, CO, USA), according to the American Thoracic Society/European Respiratory Society recommendations [21] and interpreted according to Pereira et al [22].

Finally, patients' perceptions were assessed through semi-structured individual interviews conducted by a physiotherapist (----). Five open-ended questions formulated around the participants' perceptions about asthma were used to guide the interview. Questions were prepared to capture perceptions of adults with asthma about their disease and health domains during their spontaneous discourse, aiming to find and validate the most relevant categories and components of the ICF Core Sets. Specifically, patients were asked about i) their asthma concept: "*What is asthma for you?*"; ii) the overall impact of asthma in their life: *''How do you feel about living with asthma?"*; iii) asthma symptoms: *"From your point of view, what are the main symptoms of asthma?"*; iv) triggers that worsen symptoms: *"What situations can make your symptoms worse?"*; and v) their last exacerbation: *"When and how did your last exacerbation happen?"*. Participants were explained that exacerbation meant the need for a medical visit due to significant worsening of symptoms, increased medication dosage and/or changes in the prescribed medication [2]. Each interview lasted approximately 20 minutes.

Data analysis

Descriptive statistics, i.e., the means ± standard deviations and absolute number (percentage), were used to describe the socio-demographic and clinical characteristics of participants. Then, a qualitative analysis of the interviews was performed by two independent researchers with

expertise in the ICF framework (---- and ----), using the meaning condensation procedure [23]. First, two researchers read the transcripts for a general impression of the interviews. Then each researcher divided the data into meaning units (words or sentences) about the same theme. The condensation of the units was performed linking the meaning units to specific concepts. Finally, the concepts in each meaning unit were identified and linked to the ICF categories according to the defined linking rules [24,25]. If an identified concept was not sufficiently specified to decide which ICF category to link it to, the concept was coded "not defined"; and if a concept was not represented by ICF as a whole, the concept was labelled "not covered" [26]. After each researcher had independently identified the concepts and respective ICF categories, the final decision about including an ICF category was based on consensus. If a consensus could not be reached, a third researcher (----) was consulted.

The identified ICF categories were compared with the categories of the current versions of the Comprehensive (67 second-level and 4 third-level categories) and Brief (17 second-level categories) ICF Core Sets for OPD [10]. The Comprehensive ICF Core Set has the ability to collect more information, and it is indicated for multidisciplinary assessments in the rehabilitation process [10,14]. The Brief ICF Core Set is composed of the minimum data to be used in any clinical context [10,14]. Categories included in the Comprehensive or Brief ICF Core Set for OPD were confirmed if the same category emerged from the interviews; and so they were called as "confirmed". The second level categories of the ICF Core Sets were also confirmed when the corresponding third or fourth level category was identified [27]. When a category included in the current versions of the ICF Core Sets did not emerge from the interviews, it was labelled as "not confirmed". The "added" categories were those identified in the interviews, that were possible to link to the ICF as a whole, but that were not part of the current versions of the ICF Core Sets for OPD.

The interviews of all participants were analysed to ensure a larger range of ICF categories identified. Nevertheless, data saturation was assessed in the last five interviews to ensure that no additional second level ICF categories of the Comprehensive ICF Core Set for OPD had emerged [27]. The consistency of the qualitative analysis between the two researchers was evaluated using an inter-observer reliability analysis (Cohen's kappa), considering each level of the ICF [28]. The Cohen's kappa analysis was performed using 15% of the interviews (randomly selected from the Random Lists website - https://www.randomlists.com/random-numbers). This analysis was performed by the third researcher (----). The agreement level was classified as follows: slight (0.0-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80) or almost perfect (≥0.810) [28]. All statistical analyses were performed using the IBM SPSS Statistics version 24.0 (SPSS Inc., Chicago, IL, USA).

Results

Participants

Forty-six adults with asthma were eligible and invited to participate in the study. Nine patients were not included due to the following reasons: six did not present the minimal required Asthma Control Test score (i.e., > 18 points) [20], and three failed to attend the appointment. Two patients were excluded because one had a psychiatric condition, and one withdrew when the written consent was obtained. Of the 35 remaining participants, 74.3% were females (n=26) and 40% were overweight (n=14). Most participants used inhaled steroids on a regular basis (88.6%; n=31) and short-acting bronchodilators on an as-needed basis to treat exacerbations (65.7%; n=23). Long-acting bronchodilators were used by 13 participants (37.14%) and leukotriene modifiers by two participants (5.7%). None of them were enrolled in a pulmonary rehabilitation program and none of them were currently

smokers. Seven participants were former smokers (20%), having smoked during an average of 3.5±1.89 years and stopped on average 13.4±9.9 years ago. Table 1 presents the sociodemographic, anthropometric and clinical characteristics of the participants.

[Table 1 near here]

Data saturation and inter-observer agreement

Data saturation has been reached, as in the last five interviews, no additional second level ICF categories of the Comprehensive ICF Core Set for OPD emerged. The inter-observer agreement was substantial for the ICF component (Kappa=0.78; 95% CI 0.67-0.88) and the first (Kappa=0.78; 95% CI 0.70-0.90), second (Kappa=0.78; 95% CI 0.70-0.90) and third (Kappa=0.62; 95% CI 0.43-0.71) levels; and almost perfect for the fourth level (Kappa=0.83; 95% CI 0.66-0.99).

Identified ICF categories

From interviews, a total of 405 concepts were identified. Of these, 348 concepts were linked to the following 61 ICF categories: 25 from the second level, 33 from the third level and 3 from the fourth level. Considering the total number of linked concepts, 168 (48.3%) were from the Body Functions component; 22 (6.3%) from the Body Structures component; 33 (9.5%) from the Activities and Participation component; and 125 (35.9%) from the Environmental Factors component.

The ICF categories identified from the Body Functions and Body Structures are shown in table 2, those from the Activities and Participation are in table 3, and those from the Environmental Factors are in table 4. These tables also show the confirmed and added categories regarding to the Comprehensive ICF Core Set for OPD.

[Tables 2, 3 and 4 near here]

Comprehensive ICF Core Set

Altogether, the identified ICF categories confirmed 29 (41%) of the 71 categories included in the Comprehensive ICF Core Set for OPD. Eleven additional second level categories that are not currently included in the Comprehensive ICF Core Set for OPD were identified from the participants' perspective as follows: 4 from the Body Functions component (b126, b439, b469 and b510); 2 from the Activities and Participation component (d299 and d415) and 5 from the Environmental Factors component (e135, e220, e299, e350 and e399). Additional third level categories were also identified as follows: 9 from the Body Functions component (b1263, b1265, b1266, b1301, b4301, b4402, b4552, b5105, and b5106); 1 from the Body Structures (s43010), 8 from the Activities and Participation component (d2401, d4150, d4551, d5701, d5702, d6402, d8451 and d8452) and 13 from the Environmental Factors component (e1100, e1101, e1150, e1350, e1351, e1551, e2200, e2201, e2250, e2251, e2600, e2601, and e5800). Three fourth level categories were also identified as follows: 2 from Body Functions (b28010 and b28011), and 1 from Body Structures (s43010). Among the confirmed and added ICF categories from the second level, 12 were reported by more than 30% of the participants as follows: 7 in Body Functions, 1 in Body Structures, 1 in Activities and Participation and 3 in Environmental Factors.

Forty-two (59%) categories were not confirmed, 9 from the Body Functions component (b134, b310, b410, b430, b445, b530, b730, b740, b780), 4 from the Body Structures component (s410, s710, s720, s760), 14 from the Activities and Participation component (d330, d410, d460, d465, d470, d475, d4750, d510, d540, d620, d650, d660, d770, d910), and 15 from the Environmental Factors component (e120, e150, e245, e2450, e320, e340, e355, e420, e450, e460, e540, e555, e575, e585, e590).

Brief ICF Core Set

Regarding the Brief ICF Core Set for OPD, the identified ICF categories confirmed 13 (77%) of the 17 categories included in this version. Four categories were not confirmed as follows: 1 from the Body Functions component (b740), 2 from the Body Structures component (s410, s760) and 1 from the Activities and Participation component (d540).

Concepts not linked to the ICF

A total of 57 concepts could not be linked to the ICF. Twenty-two were coded as Personal Factors, mainly related to age, habits, coping strategies, social background and past/current experiences. Eleven were coded as "not covered", including "muffled place", "sputum", and "asthma attack"; and 9 as "not defined", when participants were characterising their asthma/symptoms, e.g., "too bad" and "horrible". Fifteen concepts were related to the health condition ("respiratory disease", "inflammation", "infection" and "bronchitis").

Discussion

This study confirmed approximately 40% and 80% of the categories included in the Comprehensive and Brief ICF Core Sets for OPD, respectively. This result contrasts with studies that validated Comprehensive ICF Core Sets for other chronic conditions, such as rheumatoid arthritis [27], diabetes mellitus [29], fibromyalgia [30], stroke [31] and COPD [18], which confirmed a greater number of categories. Several reasons may explain this finding. First, there are clear differences between the present study and these previous studies, mainly related to the methods used (individual interviews vs. focus groups) to assess the perspective of patients [32]. Second, whilst the ICF Core Set for OPD integrates specific categories useful for distinct OPD, the reported ICF Core Sets are specific for a single disease. Third, our questions emphasised the impact of the disease and a general approach; in

previous studies [18,27,29-31], questions were more specific to each ICF component. Finally, this study included patients with stable and controlled asthma [2,20], and it is well known that exacerbation periods have a major impact on health in these patients [1,2]. On the other hand, the categories most frequently identified by patients with asthma are present in the Brief ICF Core Set for OPD. These results are in line with previous studies in other conditions, showing that this ICF Core Set captures patient's perspective, and thus might be more suitable for use in clinical practice [33,34].

Regarding the Body Functions component, the second level categories b440 Respiration functions, b450 Additional respiratory functions, b455 Exercise tolerance functions and b460 Sensations associated with cardiovascular and respiratory functions were confirmed in the Comprehensive ICF Core Set. These categories are related to the symptoms commonly reported by patients with asthma, such as dyspnoea, fatigue, cough and chest compression [2,4], and they were reported by most participants. Moreover, these categories were the four most relevant among the five selected for the Body Functions component in the Brief ICF Core Set for OPD [10], which demonstrates high concordance between the perceptions of patients with asthma and the current version of this Core Set. Category b435 was identified by more than 30% of the participants, mainly its third level category b4351 Hypersensitivity reactions, which might be related to the potential of allergens to trigger exacerbations, especially in the allergic phenotype [2]. A significant number of concepts identified from the Body Functions component were related to the burden of disease on mental functions, such as lack of optimism and motivation, fear and anxiety, and these concepts have been identified in patients with asthma [4,36-38]. Relevant categories related to mental functions, such as b1522 Range of emotion and the correspondent b152 Emotional functions, were both identified, whilst the categories b730 Muscle power functions, b740 Muscle endurance functions and b780 Sensations related to muscles and movement functions

were not identified by adults with asthma. This result can be explained by the sample composed mostly by adults in productive age and without significant functional limitations.

As for the Body Structures component, impairments in the structures of the lungs and bronchial tree (s4301 and s43010) were identified, which correspond to the second level category s430 Structure of respiratory system. This result was probably related to the educational level of patients included (63% with complete high school or university) and confirms their understanding about how the disease affects the respiratory system. This knowledge is a key point in patients' self-management and treatment adherence [2,39].

Regarding Activities and Participation, the category d230 Carrying out daily routine was the most reported. Our results are in line with a previous report by Svedsater et al [4] who found that patients with asthma report difficulties in carrying out or avoid activities that they were able to do before, including physical exercise. Thus, the role of health professionals in reinforcing the benefits of adequate physical activity is deemed essential. Thirteen second level categories from the Activities and Participation component were not raised in the participants' views, and may reflect the absence of these activities in their routines, or an absence of limitation performing it.

Considering the Environmental Factors component, e260 Air quality and e225 Climate were the most reported by patients and were confirmed in the first version of both ICF Core Sets for OPD. Indeed, poor air quality and weather changes are related to adult onset asthma, exacerbations and mortality [2,40,41]. The relevance of these categories is further highlighted by their relevance to other OPD, which also dictated their inclusion in the Brief Core Set [10]. The category e1101 Drugs was also frequently reported by participants. The corresponding second level category e110 Products or substances for personal consumption is present in both Core Sets and received 100% agreement among the experts to be included in the Brief

ICF Core Set for OPD [10]. Our results showed that medication was reported primarily as a facilitator, which can contribute to adherence and disease control [2,4].

A substantial number of concepts were identified as Personal Factors (n=22), including race, gender, age, educational and social levels, coping strategies and life experiences. These characteristics are not specified in categories of the ICF; however, they are considered in the classification because of their influence on patients' health, including adults with asthma [3,4,6]. Thus, this study supports the development of codes for these factors in future updates of the ICF, and hopes to contribute with the concepts that have been identified.

Although the ICF has a significant number of categories, some individual experiences are not covered by this framework. Among these concepts, the "muffled place" was a new concept that emerged in the present study. This concept may be associated with the cultural characteristics of ---- patients living or working in places without adequate ventilation and moving in public transportation often tumultuous with a large number of people. A reference to sputum and its characteristics was also identified. Such reference has appeared previously in studies about asthma and COPD [35], as well as in the perspective of patients with COPD [18], physicians [15] and physiotherapists [42], revealing its importance for consideration in the next updates of the ICF.

Strengths and limitations

The linking process was done by two researchers from different countries (--- and ---) with distinct cultural backgrounds and minor language differences. Some expressions used by the interviewees were specific to their cultural context and therefore, some expressions were unknown by one of the researchers, which could have potentially introduced some bias. However, the kappa was substantial, ranging between 0.62 and 0.83, which is in accordance with the recommendations for agreement [43]. It is important to consider that the included

patients were only from ----, had stable asthma and were never/former smokers, and they may in turn have different perspectives from patients from other countries, during or shortly after exacerbation periods or current smokers.

In the present study, the choice of using individual interviews over focus group removed the effect of group process, but may have influenced the amount of information collected. The selected format of questions, not directed to specific health domains, may also have limited the comprehensiveness of the information collected, but it was a strategy to obtain the most representative experiences of patients' daily life and to minimize the influence of the researcher's perceptions. Although saturation has been achieved, it is likely that these methodological choices have contributed for a smaller number of confirmed categories than previous studies. In future studies, focus groups with questions more directly linked to ICF components could also been used, as it is a recommended methodology to validate ICF Core Sets [32].

In conclusion, almost all categories included in the Brief ICF Core Set and approximately half of the categories included in the Comprehensive ICF Core Set for OPD were confirmed by the perspective of adults with asthma. Thus, both Core Sets were supported, and the Brief one seems to be a good reference to use in clinical practice. Unconfirmed categories and those added in relation to the Comprehensive ICF Core Set have been reported, and their analysis may assist future document updates. Future studies comparing the perspective of patients with different OPD and from different countries are needed to confirm these findings and to inform future updates of the document. This will allow a more specific use of the ICF Core Sets for OPD.

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Declaration of interest

The authors report no conflicts of interest.

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Table 1. Characteristics of the participants (n=35).

Characteristics	
	mean ± SD
Age, years	41.00 ± 13.43
BMI, kg/m^2	28.24 ± 5.65
ACT, score	20.69 ± 2.80
FEV_1, % predicted	77.45 ± 16.99
	n (%)
Educational level	
Primary school	6 (17.14)
Secondary school	7 (20.0)
High school	18 (51.43)
University	4 (11.43)
Smoking status	
Former smoker	7 (20.00)
Never smoker	28 (80.00)

Data are presented as the mean ± standard deviation or number (percentage). BMI: body mass index; ACT: asthma control test; FEV_1: forced expired volume in one second.

Table 2. ICF categories identified for Body Functions and Body Structures.

ICF code	ICF category	Status
b126	Temperament and personality functions	*Added*
b1263	Psychic stability	*Added*
b1265	Optimism	*Added*
b1266	Confidence	*Added*
b130	**Energy and drive functions**	***Confirmed***
b1301	Motivation	*Added*
b152	**Emotional functions**	***Confirmed****
b1522	**Range of emotion**	***Confirmed***
b280	**Sensation of pain**	***Confirmed***
b2801	**Pain in body part**	***Confirmed***
b28010	Pain in head and neck	*Added*
b28011	Pain in chest	*Added*
b435	**Immunological system functions**	***Confirmed****
b4351	Hypersensitivity reactions	*Added*
b439	Functions of the haematological and immunological systems, other specified and unspecified	*Added*
b440	**Respiration functions**	***Confirmed**[*,b]*
b4402	Depth of respiration	*Added*
b450	**Additional respiratory functions**	***Confirmed**[*,b]*
b455	**Exercise tolerance functions**	***Confirmed**[*,b]*
b4552	Fatigability	*Added*
b460	**Sensations associated with cardiovascular and respiratory functions**	***Confirmed**[*,b]*
b469	Additional functions and sensations of the cardiovascular and respiratory systems, other specified and unspecified	*Added*
b510	Ingestion functions	*Added*
b5105	Swallowing	*Added*
b5106	Regurgitation and vomiting	*Added*
s430	**Structure of respiratory system**	***Confirmed**[*,b]*
s4301	Lungs	*Added*
s43010	Bronchial tree	*Added*

ICF: International Classification of Functioning, Disability and Health. Confirmed: ICF categories emerged from the interviews that were included in the Comprehensive ICF Core Set for Obstructive Pulmonary Diseases - shown in bold typeface. Added: ICF categories emerged from the interviews that were not included in the Comprehensive ICF Core Set. Corresponding second level categories are shown above each category, even when not directly identified. *Reported by more than 30% of the patients. [b]Also confirmed for the Brief ICF Core Set.

Table 3. ICF categories identified for Activities and Participation.

ICF code	ICF category	Status
d230	**Carrying out daily routine**	***Confirmed***,b*
d240	**Handling stress and other psychological demands**	***Confirmed***
d2401	Handling stress	*Added*
d299	General tasks and demands, unspecified	*Added*
d415	Maintaining a body position	*Added*
d4150	Maintaining a lying position	*Added*
d430	**Lifting and carrying objects**	***Confirmed***
d450	**Walking**	***Confirmed**b*
d455	**Moving around**	***Confirmed**b*
d4551	Climbing	*Added*
d570	**Looking after one's health**	***Confirmed***
d5701	Managing diet and fitness	*Added*
d5702	Maintaining one's health	*Added*
d640	**Doing housework**	***Confirmed**b*
d6402	Cleaning living area	*Added*
d845	**Acquiring, keeping and terminating a job**	***Confirmed***
d8451	Maintaining a job	*Added*
d8452	Terminating a job	*Added*
d850	**Remunerative employment**	***Confirmed***
d920	**Recreation and leisure**	***Confirmed***

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Table 4. ICF categories identified for Environmental Factors.

ICF code	ICF category	Status
e110	**Products or substances for personal consumption**	***Confirmed*[*,b]**
e1100	Food	*Added*
e1101	Drugs	*Added*
e115	**Products and technology for personal use in daily living**	***Confirmed*[b]**
e1150	General products and technology for personal use in daily living	*Added*
e135	Products and technology for employment	*Added*
e1350	General products and technology for employment	*Added*
e1351	Assistive products and technology for employment	*Added*
e155	**Design, construction and building products and technology of buildings for private use**	***Confirmed***
e1551	Design, construction and building products and technology for gaining access to facilities in buildings for private use	*Added*
e220	Flora and fauna	*Added*
e2200	Plants	*Added*
e2201	Animals	*Added*
e225	**Climate**	***Confirmed*[*,b]**
e2250	Temperature	*Added*
e2251	Humidity	*Added*
e260	**Air quality**	***Confirmed*[*,b]**
e2600	Indoor air quality	*Added*
e2601	Outdoor air quality	*Added*
e299	Natural environment and human-made changes to environment, unspecified	*Added*
e310	**Immediate family**	***Confirmed***
e350	Domesticated animals	*Added*
e399	Support and relationships, unspecified	*Added*
e410	**Individual attitudes of immediate family members**	***Confirmed***
e580	**Health services, systems and policies**	***Confirmed***
e5800	Health services	*Added*

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